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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/541,828

07/12/2005

Ganga Raju Gokaraju

DAD-0013

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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

01/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/541,828 | Applicant(s) GOKARAJU ET AL. | |
| | Examiner YEVEGENY VALENROD | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-16 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/5/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a final office action in application # 10/541,828.

Amendments to the claims submitted 8/27/08 are acknowledged.

Objections to claims 12-16 and 19 are withdrawn in view of applicants' amendments.

Rejection of claims 3-5, 12-16 and 19 under 35 USC 112 is withdrawn in view of applicants' amendments.

Rejection of claims 1, 2, 5 and 19 under 35 USC 102(b) is maintained

Rejection of claims 1-5, 12-16 and 19 under 35 USC 103(a) is maintained.

Text of the maintained rejections is repeated below followed by the Examiner's reply to Applicants' remarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Shrivastava et al. (US 6,221,901). Shrivastava et al describe preparing Magnesium (-)hydroxycitrate with at least one metal, said metal includes zinc. Although Shrivastava et al do not explicitly describe the compound of general formula (I), said compound is

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inherently present in the solution. The inherency argument is supported by the fact that all the ingredients required to make the claimed double salt are present in the solution. Since magnesium is capable of making a salt with two anionic components, and hydroxycitric acid has 3 carboxylate groups, it stands to reason that one of the magnesium or zinc ions that forms a salt with the 3rd carboxylate groups will have to find another molecule of hydroxycitric acid in order to acquire the appropriate valency.

Claim 19 recites a limitation directed to the intended use of the double metal salt of claim 1. It is well settled that the intended use of a composition or product (e.g. as a cosmetic composition) will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount as instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d, 1647.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 12-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shrivastava et al. (US 6,221,901).

Scope of prior art

Shrivastava et al describe preparing Magnesium (-)hydroxycitrate with at least one metal, said metal includes zinc. Although Shrivastava et al do not explicitly describe the compound of general formula (I), said compound is inherently present in the solution. The inherency argument is supported by the fact that all the ingredients required to make the claimed double salt are present in the solution. Since magnesium is capable of making a salt with two anionic components, and hydroxycitric acid has 3 carboxylate groups, it stands to reason that one of the magnesium or zinc ions that forms a salt with the 3rd carboxylate groups will have to find another molecule of hydroxycitric acid in order to acquire the appropriate valency.

Ascertaining the difference between prior art and instant claims

Shrivastava et al. fail to teach salt combinations other than magnesium and zinc.

Obviousness

It is common in the art to make salts of carboxylic acids. One of ordinary skill in the art at the time the invention was made would have been motivated to make various

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other salts of hydroxycitric acid in order to alter the solubility of the said acid. It is well known in the art that altering the counter ion of a carboxylic acid salt can have a profound effect on the physical properties of that salt. Since Shrivastava et al. utilize their salt in a pharmaceutical composition. One skilled in the art would be motivated to alter the salts as of Shrivastava et al. in order to alter the solubility of the salt.

Reply to applicants' remarks

Applicants' remarks submitted 8/27/08 have been fully considered. The arguments presented have been found to be insufficient to overcome the rejections of record.

Concerning 35 USC 102(b)

Applicants has traversed the rejection under 35 USC 102(b) over Shrivastava. Applicant has argued that 1) Shrivastava fails to disclose the instantly claimed double metal salt of hydroxycitrate and also 2) that: Examiner has not provided "objective evidence or cogent technical reasoning to support the conclusion of inherency" (page 6 of remarks).

Examiner disagrees with applicants' argument. 1) Although Shrivastava fails to disclose the instantly claimed double metal salt, it is the Examiners position that the said salt is inherently present in the arts composition (see claim 1 of Shrivastava). 2) The inherency argument, based on cogent technical reasoning, has been presented in the body of the rejection: "The inherency argument is supported by the fact that all the ingredients required to make the claimed double salt are present in the solution. Since magnesium is capable of making a salt with two anionic components, and hydroxycitric

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acid has 3 carboxylate groups, it stands to reason that one of the magnesium or zinc ions that forms a salt with the 3rd carboxylate groups will have to find another molecule of hydroxycitric acid in order to acquire the appropriate valency.” To elaborate further although not all of citric acid can be expected to be in the instantly claimed salt, the examiners position is that with all of the required ingredients present at least some of the salts formed would be of the instantly claimed form. Furthermore, claims 1, 2, and 19 do not require for two different metals to be present, the double metal salt can be formed with just magnesium (-)hydroxycitrate in solution.

Concerning 35 USC 103(a)

Applicants have traversed the rejection under 35 USC 103(a) on the grounds that:

- 1) No cogent technical reasoning has been provided for the inherency argument.
- 2) It is not obvious to substitute metal counterions in salts because the property of the resulting salt can be different from the original.

Examiner disagrees with applicants' assertion regarding both of the above arguments.

- 1) As stated above, the technical reasoning for the inherency argument has been provided (see reply to the arguments concerning 35 USC 102(b)).
- 2) The very reason that the properties of the salt can be altered by choosing different counterions serves as motivation for making various salts. Doing so falls under the umbrella of optimization of pharmaceutical compositions and since the compositions of Shrivastava are pharmaceutical compositions altering the nature of the salt is a way to

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optimize the compositions properties. This rejection can be overcome by a showing that the specific salt claimed by the applicant possesses unexpected properties.

3) Regarding treatment of osteoporosis. Ability to treat Osteoporosis is inherently present in the salts of Shrivastava. The said ability is a property of the compound. Compound and its properties are inseparable.

Conclusion

Claims 1-19 are pending.

Claims 6-11 and 17-18 are withdrawn.

Claims 1-5, 12-16 and 19 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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